REMARKS

Claims 3, 4, 7, 10, 27, 33, 35-37, 54, 57, 58, and 61-74 are presently pending. Claims 62, 64, 65 and 67 have been cancelled herein without prejudice. Claims 68-72 and 74 stand withdrawn from consideration as directed to a non-elected species. Claims 3, 4, 7, 10, 27, 33, 35-37, 54, 57, 58, and 61, 63, 66 and 73 will be pending and under examination in this application upon entry of this amendment. Applicants respectfully traverse all grounds for rejection.

Regarding 35 U.S.C. § 112, First Paragraph (Written Description)

Applicants respectfully traverse the rejection of claims 3, 4, 10, 36, 57, 58, 61, 62, 64-67 and 73 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, had possession of the claimed invention at the time the application was filed.

Regarding claims 3, 4, 10, 36, 57, 58, 61, 62, 64-67 and 73

The Examiner has rejected claims 3, 4, 10, 36, 57, 58, 61, 62, 64-67 and 73 under 35 U.S.C. § 112, first paragraph, over the term "different bead." It is allegedly unclear from the disclosure whether the "first and second beads" can be different either in size or by virtue of having different oligonucleotide sequences attached.

Applicants respectfully submit that there is nothing in the specification that suggests that the term "first and second beads," is meant to be limited to identical beads. Rather, the specification is consistent with an interpretation of the phrase "first and second beads" that allows for differences, including, for example, in size or oligonucleotide sequences, between the "first and second beads." As set forth in the MPEP at §2111, during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard." Here, the specification discusses, for example, various ranges of "bead sizes," as opposed to ranges of "bead size" in the singular form. Specification, p.18, fourth paragraph. On its face, this language is consistent with the interpretation that the

beads can have varying sizes and, accordingly, the MPEP and the reviewing courts have made clear that the claims must be given the broadest possible consistent interpretation.

Similarly, with regard to whether the phrase "first and second beads" is consistent with the first and second beads having different nucleotides attached, both the common interpretation and the specification are in accord as neither limits the "first and second beads" to beads having identical oligonucleotide sequences attached. On the contrary, consistent with the broadest interpretation, the specification discloses, for example, that the oligonucleotides that are ultimately attached can be synthesized randomly so as to generate pools comprising randomly generated oligonuclotides. It is consistent with the interpretation of "first and second beads" allowing for different oligonucleotides that the specification envisions synthesis of a random pool of oligonucleotides that are subsequently attached to the beads. Specification, page 20, fourth paragraph.

In view of the above arguments and the mandate that the pending claims must be "given their broadest reasonable interpretation consistent with the specification," Applicants respectfully request removal of this ground for rejecting claims 3, 4, 10, 36, 57, 58, 61, 62, 64-67 and 73 under 35 U.S.C. § 112, first paragraph, over the term "different bead."

Regarding claims 62 and 65

The Examiner has further rejected claims 62 and 65 as lacking written description under 35 U.S.C. § 112, first paragraph, because the element "substrate comprises greater than 400 different nucleotides" allegedly lacks support in the specification. According to the Examiner, the specification provides support for 400 loci, but not for more than 400 loci. Without conceding the merit of the rejection, Applicants have cancelled claims 62 and 65. Applicants reserve the right to pursue the cancelled subject matter at a later time.

Regarding claims 64 and 67

The Examiner has further rejected claims 64 and 67 as lacking written description under 35 U.S.C. § 112, first paragraph, because the element "substrate comprises greater than 2000 different nucleotides" allegedly lacks support in the specification. According to the Examiner, the specification provides support for 2000 loci, but not for more than 2000 loci. Without

conceding the merit of the rejection, Applicants have cancelled claims 64 and 67. Applicants reserve the right to pursue the cancelled subject matter at a later time.

Rejections Under 35 U.S.C. § 103

Applicants respectfully traverse the rejection of claims 7, 10, 27, 33, 35-37, 57, 58, 61-67 and 73 are unpatentable under 35 U.S.C. § 103 as obvious over Wang et al., *Science* 280:1077-1082 (1998) ("Wang et al.") and U.S. Patent No. 6,013,440 to Lipshutz et al. ("Lipshutz et al."), as evidenced by Lashkari et al., *Procl. Nat. Acad. Sci. USA* 92:7912-7915 (1995) ("Lashkari et al."), Sinha et al., *Nucl. Acids Res.* 12:4539-4557 (1984) ("Sinha et al.") and Weiler et al. *Anal. Biochem.* 243:218-227 (1996) ("Weiler et al.").

Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) *See also Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207-08, 18 USPQ2d 1016, 1022-23 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success.).

"A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994); see *KSR*, 127 S. Ct. 1727 (2007), at 1739–40 (explaining that when the prior art teaches away from a combination, that combination is more likely to be nonobvious). References that teach away cannot serve to create a *prima facie* case of obviousness. *In re Gurley*, 27 F.3d at 553. If references taken in combination would produce a "seemingly inoperative device," the Federal Circuit has held that such references teach away from the combination and thus cannot serve as predicates for a *prima facie* case of obviousness. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001); *In re Sponnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (CCPA 1969) (references teach away from combination if

combination produces seemingly inoperative device); *see also In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (inoperable modification teaches away).

The Office Action mailed December 23, 2008, concedes that the primary Wang et al. reference does not teach the required claim element of obtaining the primers from a pool of oligonucleotides released from a support it was synthesized on. However, the Office Action concludes that the skilled person would have replaced the standard synthesis method of Wang et with the method of pool synthesis of Lipshutz et al. in view of clear evidence from Weiler et al. that the primers could be used directly after cleavage from support, therefore saving time and expense required for purification of oligonucleotides obtained from standard synthesis.

Applicants respectfully submit that the skilled person would not have modified the standard synthesis method of Wang et al. with the method of pool synthesis of Lipshutz et al. in view Weiler et al. or any of the other cited references.

The Wang et al. reference communicates repeatedly the importance of individual primer optimization. In this regard, Wang et al. expressly rely on empirical assays using individual primers to optimize conditions prior to carrying out a multiplex amplification step. (first paragraph at page 1080, first paragraph) Furthermore, Wang et al. describe that the primers were initially selected using the PRIMER software package to maximize factors that affect SNP genotyping success and explain that "[e]ach PCR primer pair was *individually tested* to determine if it produced a single clear fragment visible by agarose gel electrophoresis . . ." (footnote 25 at page; emphasis supplied) The operability of the method of Wang et al. requires adjusting individual primer parameters: "Each assay was tested to ensure that it amplified a single fragment from genomic DNA (page 1080, left column, first paragraph). Wang et al. further state that "the success appears to have resulted from a combination of factors, including the small amplification targets, *optimization of amplification conditions*, and the presence of constant sequence at the 5'-ends of the primers." (page 1080, right hand column, first paragraph).

Lipshutz et al. patent describes nucleic acid pools that comprise a heterogeneous collection of different nucleic acids and, by attaching the pool(s) of nucleic acids to a solid support, a method of preparing nucleic acid arrays. The nucleic acid pools and arrays described

by Lipshutz et al. are designed to simultaneously bind to and capture a large number of different nucleic acids.

Lashkari et al. describe a 96 well automated multiplex oligonucleotide synthesizer (A.M.O.S.) that is capable of making thousands of oligonucleotides. Sinha et al. describe methods of oligonucleotide synthesis on controlled pore glass (CPG) beads. Weiler et al. describe methods of producing oligonucleotides with variable yields.

Applicants submit herewith a Declaration by Dr. John Stuelpnagel, a co-inventor of the above-identified application. Dr. Stuelpnagel is a pioneer in the field of array-based technologies and a co-founder of Illumina. Dr. Stuelpnagel declares that the skilled person would have been disinclined to combine the Wang et al. and Lipshutz et al. references because the Lipshutz et al. pool synthesis does not allow for the individual optimization that Wang et al. require for their method's success. Attachement A, Stuelpnagel Declaration, ¶15 Dr. Stuelpnagel further declares that the skilled person reviewing the Wang et al. and Lipshutz et al. references, alone or in combination with Weiler et al. or any of the other cited references, would not have had an expectation of success and would have been led away from combining the Wang et al.'s methods with the pool synthesis of Lipshutz et al. Attachement A, Stuelpnagel Declaration, ¶15 In addition, Dr. Stuelpnagel declares that, had a skilled person been determined to replace the standard synthesis method of Wang et al., they would have encountered significant obstacles that are detailed by Dr. Stuelpnagel in his Declaration. Attachement A, Stuelpnagel Declaration, ¶16. As can be seen from Dr. Stuelpnagel's statements, the consequences of combining the cited references range from inefficiency to inoperability. Attachement A, Stuelpnagel Declaration, ¶16.

Based on the attached Declaration and the accompanying remarks herein, Applicants respectfully submit that (1) the cited references do not give rise to an expectation of success with regard to their combination resulting in the claimed invention, (2) the primary Wang et al. reference contains express teachings away from a combination with Lipshutz et al., and (3) the combination of cited references represent modifications that range from impractical to inoperable.

Applicants respectfully traverse the rejection of claims 3 and 4 under 35 U.S.C. § 103 as obvious over Wang et al., *Science* 280:1077-1082 (1998) ("Wang et al.") and U.S. Patent No. 6,013,440 to Lipshutz et al. ("Lipshutz et al."), as evidenced by Lashkari et al., *Procl. Nat. Acad. Sci. USA* 92:7912-7915 (1995) ("Lashkari et al."), Sinha et al., *Nucl. Acids Res.* 12:4539-4557 (1984) (Sinha et al.") and Weiler et al. *Anal. Biochem.* 243:218-227 (1996) ("Weiler et al.") as applied to claims 27, 34, 35 and 61, and further in view of Nelson et al., Nucl. Acids Res. 20:6253-6259 (1992) ("Nelson et al."). The rejection of claims 3 and 4 relies primarily on the primary references by Wang et al. and Lipshutz et al. The deficiencies of this combination are detailed above and in the attached Declaration. The secondary references do not address, much less cure these deficiencies, which are fatal to the instant obviousness rejection. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 3 and 4 under 35 U.S.C. § 103 as obvious over Wang et al. and Lipshutz et al., as evidenced by Lashkari et al., Sinha et al., and Weiler et al., as applied to claims 27, 34, 35 and 61, and further in view of Nelson et al.

Applicants respectfully traverse the rejection of claim 54 under 35 U.S.C. § 103 as obvious over Wang et al., *Science* 280:1077-1082 (1998) ("Wang et al.") and U.S. Patent No. 6,013,440 to Lipshutz et al. ("Lipshutz et al."), as evidenced by Lashkari et al., *Procl. Nat. Acad. Sci. USA* 92:7912-7915 (1995) ("Lashkari et al."), Sinha et al., *Nucl. Acids Res.* 12:4539-4557 (1984) (Sinha et al.") and Weiler et al. *Anal. Biochem.* 243:218-227 (1996) ("Weiler et al.), U.S. Patent No 6,327,410 to Walt et al. ("Walt et al.") and Michael et al., Anal. Chem. 70:1242-1248 (1998). The rejection of claim 54 relies primarily on the primary references by Wang et al. and Lipshutz et al. The deficiencies of this combination are detailed above and in the attached Declaration. The secondary references do not address, much less cure these deficiencies, which are fatal to the instant obviousness rejection. Accordingly, Applicants respectfully request withdrawal of the rejection of claim 54 under 35 U.S.C. § 103 as obvious over Wang et al. and Lipshutz et al., as evidenced by Lashkari et al., Sinha et al., Weiler et al., Walt et al. and Michael et al.

CONCLUSION

In light of the Amendments, Declaration and Remarks herein, Applicants submit that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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Docket No.: 067234-0110 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Customer Number: 41552
Stuelpnagel, John, et al.	:	Confirmation Number: 6751
Application No.: 09/642,068	:	Group Art Unit: 1637
Filed: August 18, 2000	:	Examiner: Teresa E. Strzelecka

For: COMPOSITIONS AND METHODS FOR PREPARING OLIGONUCLEOTIDE SOLUTIONS

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, John R. Stuelpnagel, declare as follows:

1. I am named as a co-inventor of the above-identified patent application.

2. I received a B.S. in Biochemistry and a Doctorate in Veterinary Medicine from the University of California, Davis and an M.B.A. from the University of California, Los Angeles..

3. I co-founded Illumina Inc. in 1998, and subsequently held various positions at Illumina until April 2008. Most recently, I served as its Chief Operating Officer from January 2005 to April 2008. I also served as a Director of Illumina, Inc. from April 1998 until April 2008. Illumina's core technologies include, *inter alia*, its bead microarray and single-base extension sequencing platforms, its various assay technologies, and its high-throughput oligonucleotide synthesis capabilities. Illumina applies these technologies to sequencing, single nucleotide polymorphism genotyping, gene expression profiling, epigenetics and proteomics. I am a co-inventor of 32 issued patents worldwide, including 11 U.S. patents, as well as on

EXHIBIT A

numerous domestic and international pending patent applications, all of which are integral to Illumina's core technologies.

6. I understand that the following factors are considered in making an obviousness determination: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of skill in the pertinent art; and (4) secondary factors of unobviousness. It has been explained to me that, where it is argued that the prior art would have motivated one of ordinary skill to arrive at the claimed invention, a number of requirements must be satisfied to render obvious a claimed invention. First, the prior art must teach or suggest all the limitations of the invention as described by the claims. Second, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. Third, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. I further understand that an explicit suggestion to combine the prior art is not necessary. Rather, the motivation to combine may be implicit and may be found in the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. I also understand that hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

7. I understand that motivation is considered to be lacking where the state of the art at the time of the invention pointed the skilled person in a different direction than the inventor proceeded. In this regard, proceeding contrary to the accepted wisdom in the art represents evidence of unobviousness. Thus, if the art contains a "teaching away" from the claimed invention, such a teaching away is an indicator of the unobviousness of the claimed invention. I further understand that if an independent claim is unobvious over a combination of references, any claims that depend on the independent claim are unobvious as well.

8. I have carefully read the Office Action mailed December 23, 2008, and reviewed each of the cited references. I understand that claims 7, 10, 27, 33, 35-37, 57, 58, 61-67 and 73 are rejected under 35 U.S.C. § 103 as obvious over Wang et al., *Science* 280:1077-1082 (1998) ("Wang et al.") and U.S. Patent No. 6,013,440 to Lipshutz et al. ("Lipshutz et al."), as evidenced

by Lashkari et al., *Procl. Nat. Acad. Sci. USA* 92:7912-7915 (1995) ("Lashkari et al."), Sinha et al., *Nucl. Acids Res.* 12:4539-4557 (1984) ("Sinha et al.") and Weiler et al. *Anal. Biochem.* 243:218-227 (1996) ("Weiler et al.). Claims 3 and 4 stand similarly rejected under 35 U.S.C. § 103 as obvious over Wang et al., *Science* 280:1077-1082 (1998) ("Wang et al.") and U.S. Patent No. 6,013,440 to Lipshutz et al. ("Lipshutz et al."), as evidenced by Lashkari et al., *Procl. Nat. Acad. Sci. USA* 92:7912-7915 (1995) ("Lashkari et al."), Sinha et al., *Nucl. Acids Res.* 12:4539-4557 (1984) ("Sinha et al.") and Weiler et al. *Anal. Biochem.* 243:218-227 (1996) ("Weiler et al.) as applied to claims 27, 34, 35 and 61, and further in view of Nelson et al., Nucl. Acids Res. 20:6253-6259 (1992). Finally, claim 54 stands rejected as unpatentable under 35 U.S.C. § 103 as obvious over Wang et al., *Science* 280:1077-1082 (1998) ("Wang et al.") and U.S. Patent No. 6,013,440 to Lipshutz et al. ("Lipshutz et al."), as evidenced by Lashkari et al., *Procl. Nat. Acad. Sci. USA* 92:7912-7915 (1995) ("Lashkari et al."), Sinha et al., *Nucl. Acids Res.* 12:4539-4557 (1984) ("Sinha et al.") and Weiler et al. *Anal. Biochem.* 243:218-227 (1996) ("Weiler et al.), U.S. Patent No 6,327,410 to Walt et al. ("Walt et al.") and Michael et al., Anal. Chem. 70:1242-1248 (1998).

10. For the reasons summarized in this paragraph and detailed in the paragraphs that follow, it is my opinion that, based on the cited references, the skilled person would have had no motivation to combine the cited references. It is my opinion that a person of skill in the art would not have had a reason to combine the Wang et al. and Lipshutz et al. references. The Lipshutz et al. pool synthesis does not allow for the individual optimization that Wang et al. expressly state to be an important factor for their method's success. Therefore, a skilled person would expect the operability of Wang et al.'s method to be compromised if modified by the pool synthesis described by Lipshutz et al., which describes the release of oligonucleotides into a pool. The pool synthesis described by Lipshutz et al. precludes individual detection and, therefore, individual optimization. Accordingly, the skilled person would have been discouraged from modifying Wang et al.'s methods with the pool synthesis of Lipshutz et al.

11. The primary reference by Wang et al. describes reliance on empirical assays using individual primers to optimize conditions prior to carrying out a multiplex amplification step. This is described in the first paragraph at page 1080, and in particular the reference to footnote 25, which describes that the primers were initially selected using the PRIMER software package

to maximize factors that affect SNP genotyping success. Footnote 25 further explains that "[e]ach PCR primer pair was individually tested to determine if it produced a single clear fragment visible by agarose gel electrophoresis . . ." The operability of the method of Wang et al., by the authors' own admission, requires adjusting individual primer parameters: "Each assay was tested to ensure that it amplified a single fragment from genomic DNA" Wang et al., page 1080, left column, first paragraph. Wang et al. further state that "the success appears to have resulted from a combination of factors, including the small amplification targets, optimization of amplification conditions, and the presence of constant sequence at the 5'-ends of the primers." Wang et al., page 1080, right hand column, first paragraph.

12. The Lipshutz et al. patent describes nucleic acid pools that comprise a heterogeneous collection of different nucleic acids and, by attaching the pool(s) of nucleic acids to a solid support, a method of preparing nucleic acid arrays. The nucleic acid pools and arrays described by Lipshutz et al. are designed to simultaneously bind to and capture a large number of different nucleic acids. As explained in more detail below, it is my opinion that Lipshutz et al.'s methods do not provide for the optimization of individual primer concentrations that are identified by Wang et al. as being a prerequisite for the amplification.

13. With regard to the secondary references, Lashkari et al. describe a 96 well automated multiplex oligonucleotide synthesizer (A.M.O.S.) that is capable of making thousands of oligonucleotides. Sinha et al. describe methods of oligonucleotide synthesis on controlled pore glass (CPG) beads. Weiler et al. describe methods of producing oligonucleotides with variable yields. Weiler et al. give no indication that the concentration of oligonucleotides produced in the solid phase synthesis methods would be known from the amount of material entering the synthesis, nor that oligonucleotides of different length or composition would have similar yields.

14. The Office Action mailed December 23, 2008, concedes that the primary Wang et al. reference does not teach the required claim element of obtaining the primers from a pool of oligonucleotides released from a support it was synthesized on. The Office Action cites Lipshutz et al., alleged to teach a method of obtaining oligonucleotide pools, to supply the missing claim element of obtaining the primers from a pool of oligonucleotides released from a support it was

synthesized on. The Office Action concludes that the skilled person would have replaced the standard synthesis method of Wang et al with the method of pool synthesis of Lipshutz et al. in view of clear evidence from Weiler et al. that the primers could be used directly after cleavage from support, therefore saving time and expense required for purification of oligonucleotides obtained from standard synthesis.

15. I respectfully disagree with the reasoning put forth and conclusion reached in the Office Action that the skilled person would have replaced the standard synthesis method of Wang et al. with the method of pool synthesis of Lipshutz et al. in view Weiler et al. or any of the other cited references. As described above in paragraph 11, the Wang et al. reference communicates repeatedly the importance of individual primer optimization. It is my opinion, that the skilled person would have been disinclined to combine the Wang et al. and Lipshutz et al. references because the Lipshutz et al. pool synthesis does not allow for the individual optimization that Wang et al. expressly state to be an important factor in their method's success. Therefore, a skilled person would expect the operability of Wang et al.'s method to be compromised if modified by the pool synthesis described by Lipshutz et al., which involves release of the oligonucleotides into a pool that precludes individual detection and, therefore, individual optimization. Looking at the two references, alone or in combination with Weiler et al.[1] or any of the other cited references, the skilled person would not have had an expectation of success and would have been discouraged from combining the Wang et al.'s methods with the pool synthesis of Lipshutz et al.

16. Assuming, for argument's sake, that a skilled person had been determined to replace the standard synthesis method of Wang et al., it is my opinion that they would have encountered significant obstacles. First, given that it is not knowable at the outset which primers need to be optimized, the oligonucleotides would have to be individually synthesized, tested and then optimized. At this point, an oligonuclotide pool has already been prepared and a reason to re-synthesize the oligonucleotides on an array per Lipshutz et al.'s method would be largely lacking. Second, once individual primer optimizations have been empirically determined, re-synthesis on an array per Lipshutz et al.'s method would not allow for reproducing the primer

[1] Weiler et al. give no indication that the concentration of oligonucleotides produced in the solid phase synthesis methods would be known from the amount of material entering the synthesis, nor that oligonucleotides of different length or composition would have similar yields.

optimizations because varying rates of synthesis and release efficiencies are inherent to the Lipshutz et al. array method. Third, a skilled person would not have considered the path of individual synthesis and optimization followed by re-synthesis on a Lipshutz et al. array to be a viable option as it drastically diminishes the efficiency and cost of the entire method in a technology area where a high premium is placed on time and cost efficiency.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statement may jeopardize the validity of the application or any patent issued thereon.

John R. Stuelpnagel

June 7, 2009

John R. Stuelpnagel

Date

SDO 149227-1.067234.0110